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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,970	08/22/2003	Morteza Naghavi	D8562-16	8386

25397 7590 05/19/2006

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EXAMINER
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HORWAT, JENNIFER A

ART UNIT	PAPER NUMBER
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3768

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/645,970

Applicant(s)

NAGHAVI ET AL.

Examiner

Jennifer Horwat

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/24/03 5/07/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Objections*

1. Claims 30, 32, and 33 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 30 is dependent on claim 31, claim 32 is dependent on claim 33, and claim 33 is dependent on itself. For the purpose of examination, dependency was interpreted as follows: Claim 30 dependent on 29, Claim 32 dependent on 31, and Claim 33 dependent on 32.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3-12, 14, 17, 19-26, and 31-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Iatrou, et al (US 2004/0136491). Iatrou discloses a method and system for detecting components of plaque to determine the composition of plaque including areas of calcified plaques, which include a high concentration of calcium,

wherein calcified plaques have a density over 120 HU (paragraph 17). The composition of plaque is believed to indicate the risk of acute coronary syndromes. Composition density distributions are calculated based on the CT data generated and may be calculated by a thresholding method that distinguishes pixels with a density greater than a chosen value (paragraph 37). CT data is obtained using any number of known CT systems, such as a third-generation CT system or a helical scan, also known as a spiral CT (paragraphs 19-21). A multi-slice detector array includes a plurality of parallel detector rows of detector elements (paragraph 25) such that two or more slices may be acquired simultaneously. Data is acquired and stored and used for reconstruction of images (paragraph 26). It is inherent in a CT system that the energy attenuation for each pixel in a scanned region is calculated. A variety of analyses are disclosed for manipulation of data obtained, including calculating total plaque burden, which is a weighted sum of densities (paragraph 37). A mapping of the coronary artery may be done using the calcification data (paragraphs 34 and 35) so that the data obtained may be visualized. The system consists of a CT scanner (figure 1, element 10), a data acquisition module (element 32), an image reconstructor (element 34), a computer for analyzing the data to determine distribution of the calcification (element 36), and storage (element 38).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over latrou in view of Hainfeld, et al (US 6818199). latrou, as discussed above, substantially discloses the invention as claimed. While latrou discloses the use of a CT (EBCT) system, latrou fails to explicitly disclose the use of an electron beam computed tomography. Hainfeld discloses a method for enhanced medical imaging and further teaches that electron beam computed tomography uses a rapid x-ray scanner, which can freeze the heart beating motion, to visualize calcification in the coronary arteries without the use of dyes or cauterization (col 3, lines 10-14). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of latrou in light of the teachings of Hainfeld to include an EBCT system in addition to the several CT systems disclosed by latrou, as Hainfeld teaches that an EBCT system is faster than traditional CT systems and provides improved visualization of a moving heart (col 3).

5. Claims 13, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over latrou in view of Li (US 6996262). latrou, as discussed above, substantially discloses the invention as claimed. While latrou discloses calculation of a statistic of the data, latrou fails to explicitly disclose the calculation of one of: mean, median, mode, standard deviation, range, coefficient of variation, skew, or kurtosis. Li also discloses a method and apparatus of scoring an arterial obstruction, such as a calcium plaque region, and further teaches statistical manipulation of the data, such as

Art Unit: 3768

determination of the maximum CT number on an image slice and determining the mean CT number for the calcification region to determine an effective density (col 8, lines 13-40). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of latrou in light of the teachings in the reference by Li to include calculation of a mean CT number so that the effective density may be obtained to provide additional information to the clinician regarding properties of the calcification.

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over latrou in view of O'Brien, et al (US 2004/0057955). latrou, as discussed above, substantially discloses the invention as claimed. While latrou discloses mapping the calcified plaque in a vessel to determine risk of cardiovascular disease, latrou fails to disclose determining a progression of plaque. O'Brien discloses a method for treating calcific aortic valve disease (paragraphs 3 and 4) including monitoring the calcification and analysis of the progression of plaque. O'Brien further discloses that statistical analyses were done on data obtained from scans wherein the progression of the plaque was observed to evaluate the relationship between progression of plaque and cardiovascular risk factors (paragraphs 85 and 86). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of latrou in light of the teachings in the reference by O'Brien to include determination of progression of plaque to better characterize risk factors for cardiovascular disease.

7. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over latrou and O'Brien as applied to claim 15 above, and further in view of Rather, et al (US

6385474). latrou in view of O'Brien, as discussed above, substantially disclose the invention as claimed. While latrou discloses categorizing areas in terms of plaque constitution, neither latrou nor O'Brien explicitly disclose categorizing an area of abrupt change in elasticity as a high-risk region. Rather also discloses a method and apparatus for detection and characterization of medical pathologies, such as calcifications, and further teaches studying density and elasticity of the tissue (paragraph 13) in which microcalcifications and tissue elasticity are identified (paragraph 25). Regions where there are abrupt changes are identified and each region is classified according to determined criterion (paragraph 87). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of latrou in view of O'Brien in light of the teachings of Rather to include ascertaining regions of abrupt changes which assists in the identification of microcalcifications and tissue elasticity which signal pathology such as cancer or calcified plaque.

8. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over latrou and Li as applied to claim 28 above, and further in view of O'Brien, et al (US 2004/0057955). latrou in view of Li, as discussed above, substantially discloses the invention as claimed. While latrou discloses mapping the calcified plaque in a vessel to determine risk of cardiovascular disease, latrou in view of Li fails to disclose determining a progression of plaque. O'Brien discloses a method for treating calcific aortic valve disease (paragraphs 3 and 4) including monitoring the calcification and analysis of the progression of plaque. O'Brien further discloses that statistical analyses

were done on data obtained from scans wherein the progression of the plaque was observed to evaluate the relationship between progression of plaque and cardiovascular risk factors (paragraphs 85 and 86). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of latrou in view of Li in light of the teachings in the reference by O'Brien to include determination of progression of plaque to better characterize risk factors for cardiovascular disease.

9. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over latrou and Li in view of O'Brien as applied to claim 29 above, and further in view of Rather, et al (US 6385474). latrou in view of Li and O'Brien, as discussed above, substantially disclose the invention as claimed. While latrou discloses categorizing areas in terms of plaque constitution, latrou, Li, and O'Brien fail to explicitly disclose categorizing an area of abrupt change in elasticity as a high-risk region. Rather also discloses a method and apparatus for detection and characterization of medical pathologies, such as calcifications, and further teaches studying density and elasticity of the tissue (paragraph 13) in which microcalcifications and tissue elasticity are identified (paragraph 25). Regions where there are abrupt changes are identified and each region is classified according to determined criterion (paragraph 87). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of latrou in view of Li and O'Brien in light of the teachings of Rather to include ascertaining regions of abrupt changes which assists in the identification of microcalcifications and tissue elasticity which signal pathology such as cancer or calcified plaque.



**Conclusion**

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Horwat whose telephone number is (571) 272-2811. The examiner can normally be reached on M-Th 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER